

REMARKS/ARGUMENTS

Status of the Claims

Upon entry of the present amendment claims 1-11 and 17 are pending and presented for examination. Claims 1, 2, 6 and 9 are amended.

Support for amending claims 1, 6 and 9 to set forth that the adipocyte is “isolated and established from adipose tissue” is found, for example, on page 5, lines 22-25, in Example 1 and in Figure 1.

Support for “operably linked to a promoter sequence” is found, for example, on page 13, lines 10-13.

Support for “stably maintained in the genome” is found, for example, on page 10, lines 26-29.

No new matter is added by the present amendments, and the Examiner is respectfully requested to enter them.

Amendments to the Specification

Applicants have amended the paragraph at page 34, lines 25-36 to correct a typographical error. This typographical error is apparent when read in light of the whole context of the specification. The following sentence in the same paragraph teaches that the administration of 0.2 mL of the suspension per mouse delivers a dose of 1×10^6 cells/head. This clearly supports that the cell density should be 5×10^6 cells/mL.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1-7 and 9-11 under 35 U.S.C. § 112, second paragraph, as allegedly unclear. To the extent that the present rejection applies to the amended claims, this rejection is respectfully traversed.

“foreign gene”

The Examiner has objected to the term “foreign gene” in claim 1. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claims 1, 2, 6 and 9 to set forth a DNA sequence.

“primary culturing an adipocyte”

The Examiner further objected to the phrase “primary culturing an adipocyte” and “stably holding” in claims 6 and 9. In the interest of furthering prosecution and not out of acquiescence to the Examiner, Applicants have amended claim 6 to set forth “isolating and establishing a primary culture,” and have amended claims 6 and 9 to set forth stably maintaining a foreign DNA in the genome.

In view of the foregoing, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 102(e)

The Examiner has rejected claims 1-9 and 17 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 7,015,037 (“Furcht”). To the extent that this rejection applies to the amended claims, this rejection is respectfully traversed.

The Examiner alleges that Furcht discloses multipotent adult stem cells that can be maintained in culture in the undifferentiated state, or differentiated to form cells of multiple tissue types, as well as methods for producing the same, for therapeutic use.

Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended the claims to set forth that the adipocyte(s) of the present invention are isolated and established from adipose tissue. This is in contrast from the stem cells described by Furcht, which are derived from bone marrow.

Accordingly, Applicants submit that the claimed invention, as amended, is clearly distinct from and novel over Furcht.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claims 9-11 under 35 U.S.C. § 103(a) as allegedly obvious over Furcht in view of U.S. Patent Publication No. 2002/0076395 ("Crystal") and U.S. Patent No. 5,639,275 ("Baetge"). To the extent that this rejection applies to the amended claims, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference must teach or suggest all the claims limitations. MPEP§2143. *See also, In re Rouffet*, 47 USPQ2d 1453. The court in *Rouffet* stated that "even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination." *Rouffet* at 1459. The court has also stated that actual evidence of a suggestion, or teaching, or motivation to combine is required and the showing of a suggestion, or teaching, or motivation to combine must be "clear and particular." *In re Dembiczak*, 50 USPQ2d 1614, 1617 (1999). Further, in formulating a rejection under 35 U.S.C. § 103(a), the proposed modification cannot render a primary reference unsatisfactory for its intended purpose or change the principle of operation of a primary reference. MPEP§2143.01(V-VI). Also, the Examiner must avoid using impermissible hindsight reconstruction by applying information gleaned only from Applicant's disclosure. MPEP§2141(II)(C) and 2145(X)(A).

Here, the combined disclosures of Furcht, Crystal and Baetge do not teach or suggest all of the claims limitations. As explained above, the primary reference Furcht does not teach the implant composition of the present invention, which requires a primary cultured adipocyte which is isolated and established from adipose tissue. The disclosures of Crystal and Baetge do not supply the elements missing from Furcht.

Furthermore, the present invention, by employing primary cultured adipocytes isolated and established from adipose tissue, provides advantages over the cited art:

Primary cultured adipocytes are a homogenous cell population suitable for implantation

As shown in Example 2 of Furcht, bone marrow-derived stem cells are multipotent stem cells that differentiate into various types of cells depending on culture conditions. Thus, obtaining a homogeneous population of cells from such bone marrow-derived stem cells is difficult. In contrast, primary cultured adipocytes isolated and established from adipose tissue are composed of terminally differentiated cells, which can be obtained as a uniform cell population. As seen in Figures 1 and 4 of the present application, almost all of the cells contain lipid droplets, forming a highly homogeneous population of adipose cells. Such uniform population of adipocytes has a reduced possibility of contamination by heterogeneous cells unsuitable for implanting. By comparison, adipocytes differentiated from bone marrow-derived stem cells are likely to contain undifferentiated stem cells, which may hinder easy extirpation after implantation as needed, a beneficial aspect of the present invention. Therefore, the present invention's primary cultured adipocytes are more suitable for gene therapy than bone marrow-derived stem cells.

Collecting adipocytes is less invasive to a patient

Collecting bone marrow cells imposes a substantial burden on patients, whereas collecting adipocytes is relatively less invasive. This is supported by the teachings in the specification, for example, items (2), (6) and (7) on page 2.

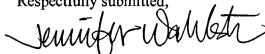
In view of the foregoing, Applicants respectfully assert that the combined disclosures of Furcht, Crystal and Baetge do not render the implant compositions obvious. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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